ATTACHMENT D

BEFORE THE

ENVIRONMENTAL PROTECTION AGENCY

TOXIC SUBSTANCES CONTROL

[40 CFR PART 700, 710]

COMMENTS OF THE

COUNCIL ON WAGE AND PRICE STABILITY

* The regulation includes an effort to maintain confidentiality of reported information. The Council recommended that this proposed procedure be strengthened to include a confidential clearance for those chemicals which form the basis of a firm's technology and are not sold commercially. Under the Council's proposal, competitive firms would not have access to this category of information.

* The Act requires that EPA undertake a premarket clearance process before new chemicals can be sold. In response to this mandate, EPA has proposed that it publish a detailed description of the new chemical along with the premarket notice in the Federal Register. The Council pointed out that in certain cases this procedure would constitute early disclosure and thus limit the patentability of the chemical. They suggested instead that EPA alter its premarket notification procedure so that a patent could be applied for after a confidential EPA review but before public notification in the Federal Register.

* EPA's proposed regulation allows exemption from the inventory requirements from small quantities of chemicals used in research and development. The Council suggested that this exemption be expanded to include chemicals tested under strict controls in user plants.

A copy of the Council's filing is attached.

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FOR IMMEDIATE RELEASE
Friday, May 13, 1977

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COUNCIL SAYS EPA RULING WOULD IMPACT ON CHEMICAL RESEARCH AND DEVELOPMENT

The Council on Wage and Price Stability today expressed concern over the impact on chemical research and development of the Environmental Protection Agency's (EPA) proposed chemical inventory requirements.

The requirements, authorized by the Toxic Substance Control Act (PL 94-496), establish procedures for collecting information from manufacturers and producers of chemicals. The Act also requires EPA testing and screening of chemical products before they are marketed.

In its filing, the Council recognized the importance of achieving the objectives to which these regulations are addressed, and supported efforts by EPA to lessen the risk of hazardous exposure to chemical substances. However, the Council noted that the reporting rules as now drafted may lead to untimely disclosure of trade secrets, and might foreclose firms from securing foreign patents. These results would reduce incentives for research by U.S. firms and possibly shift the advantage for new product development to foreign countries.

Under EPA's proposal, chemical processing and manufacturing firms would be required to submit detailed data on chemicals which could include proprietary information that forms the basis of trade secrets and potential patents. Although EPA estimated that the administrative costs of preparing the lists would be $5 million annually, they recognized but did not estimate the long-run costs that could result from reduced incentives for research.

The Council focused its comments on these long-run costs and suggested three modifications to EPA's proposal which would permit the Act's objectives to be met and still not adversely affect research and development of new chemical products. The Council raised the following points:

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efficiency with which society's resources are used and dampen the prospects for improvements in productivity. We note also that the "cost" of one regulation may be the forgone opportunity of adopting a better one. Therefore, to the extent that the proposed regulations could be improved, overall regulatory performance would be enhanced.

The Council recognizes the importance of achieving the objectives to which these regulations are addressed. Certainly we support such efforts by EPA to lessen the risk of hazardous exposure to chemical substances. Our concern lies solely with the question of whether there exist ways to improve these regulations which warrant further EPA consideration. As explained below, we believe such opportunities exist.

The Council's Comments

1. Confidentiality of Reported Information

Section 14 of the Act forbids disclosure of trade secrets and commercial information which is privileged or confidential, except for several purposes specified in the Act. This section, then, provides procedures to prevent the erosion of certain investments in basic research and proprietary knowledge gained therefrom. 1/ Despite these protections

1/ The TSCA inventory requirement is similar to those of the Food and Drug Administration with respect to products controlled by that agency. The matter of maintaining confidentiality is also a concern of FDA as well as those regulated by FDA. In a recent assessment of requests for information now available under the Freedom of Information Act, FDA indicated the receipt of some 20,000 requests in 1975 and predicted 24,000 for 1977. Of the 1975 requests which cost FDA some $1 million to process, ". . . 86 percent . . . [came] from industry and private attorneys, while only 14 percent [came] from the general public, consumers, press, health professionals, and scientists." The FDA suggested that the large bulk of these requests were associated with ". . . industrial espionage in which many commercial firms engage." [See: Food and Drug Administration, "Public Information" (42 FR 3094).]

providing documentation on confidential chemicals with EPA could place proprietary information in a less guarded environment. 1/

Section 710.6 of the proposed regulation provides that a manufacturer (or person) may assert a claim of ". . . business confidentiality concerning the chemical name or the fact he manufactures or processes a particular chemical substance for commercial purposes" (42 FR 13137). If such a claim is made, the manufacturer (or person) must furnish EPA with:

> (1) the confidential name; (2) a proposed name which is only as generic as necessary to protect the substance's confidential identity; (3) a list of the elements of the chemical substance and its molecular weight; and (4) a bibliography identifying any published literature and summaries of any unpublished information concerning the health and ecological effects and environmental behavior of the chemical substance [42 FR 13137].

The costs of compiling the above-mentioned information will tend to ration claims of confidentiality. In the absence of screening costs, those firms listing chemicals would logically claim confidentiality for a broader array of products.

There is a problem here which we would call to EPA's attention. As the cost of claiming confidentiality goes up, firms which lack

1/ A summary of current activities indicative of this problem is given in Burt Schorr, "How Law is Being Used to Pry Business Secrets from Uncle Sam's Files," Wall Street Journal, May 9, 1977, p. 1.

scientific and legal resources for securing complete documentation may be placed at a disadvantage relative to firms which already have such capabilities. This disadvantage would likely be present for only a short period. That is, consulting firms would likely develop the expertise for listing confidential products, and competition would tend to reduce the cost of listing to a cost-effective level for all firms. Even so, there will be an adjustment cost which could affect small producers.

The proposal (42 FR 13137) is designed to protect confidentiality as just noted by allowing public access only to a generic name (as distinct from a precise description) if trade secrets are involved. However, this may not provide adequate protection. Public access even to a generic name might lower the cost of identifying a trade secret. That is, inquiring firms might find it easier to gain confidential information even if less than a complete chemical name is required from an inquirer. It would seem that the burden of acquiring confidential information should fall on inquiring firms in order to preclude the unintended erosion of proprietary information. Furthermore, it would seem that the degree to which steps are taken to guard confidential information should be related to the value of that information.

The value of confidential chemicals is related to the economic life cycle of the product research and development process. An example of the life-cycle process, which includes a research and development period and a product life period, is described in Figure 1. 1/ The

1/ See Kenneth W. Clarkson, op. cit., p. 44.

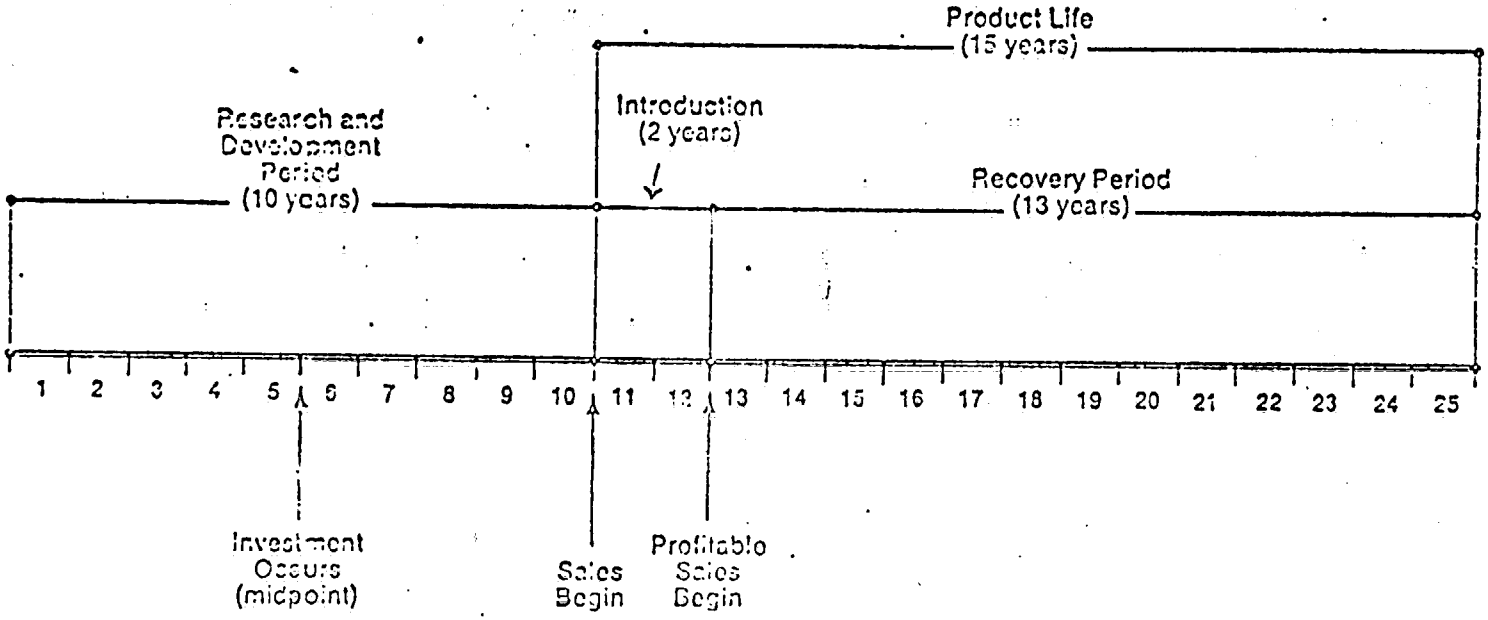

Figure 1: Economic Life Cycle for Research and Development Expenditures

Source: Vernon A. Mund, "The Return on Investment of the Innovative Pharmaceutical Firm," in Joseph Cooper, ed., The Economics of Drug Innovation (Washington, D. C.: American University, 1970), p. 131, as shown in Clarkson, op. cit., p. 44.

time values specified in Figure 1 relate to the pharmaceutical industry and are presented here strictly for illustrative purposes.

Whatever the time dimension involved, it is recognized that firms treat expenditures on research and development as they would any other investment decision. That is, expenditures are made in one period on the basis of expected future returns. Accordingly, the value of future returns which accrue over the "product" life period is discounted by the firm's cost of capital. If the expected value of profits associated with a particular project exceeded the cost of research and development expenditures, the firm would consider the project to be commercially feasible. If product life were shortened by regulatory delay, by the loss of confidential information, or for any reason, then the expected value of future profits would be reduced. Thus, an otherwise profitable project could become a losing project.

The issue of confidentiality-value relates especially to intermediates and catalysts--that is, chemical technology itself. 1/ In some cases these substances are not sold commercially, which limits significantly their exposure to the public. Hence, their exact identity cannot be determined by the end products which result from them. The

1/ We note that the importance of confidentiality may vary for other categories of products with respect to the different periods of the life cycle. For example, confidentiality may be important in the development stages of a chemical, but once the chemical is in the market, its identity soon becomes recognized. The profitable life cycle of such a product may be relatively brief. Confidentiality may be important for some substances--e.g., complex polymers--even after the market period is underway. Although such substances may be identifiable, the exact structure and its derivation may be more difficult to assess.

life-cycle value of catalysts could be quite large but would still depend on the market value of those products which result from their use. While admitting a lack of expertise in chemical manufacturing, we would expect considerable value to be attached to certain intermediate chemicals and catalysts. Listing such chemicals, even on a confidential basis, could increase the likelihood that their specific identity might be discovered.

Assuming the above logic to hold, we would recommend at least two levels of confidential treatment by EPA. To achieve the goals of confidentiality expressed in the Act, we would suggest that EPA consider the merits of the following modification. First, catalysts and intermediate chemicals which form the basis of a firm's technology would be described to EPA in sufficient detail to make a determination of their toxicity or health-environmental risk. Additional documentation would be required to identify the exposure of the process or chemical to unsuspecting populations. Then, certification would be required by a corporate official or bonded agent stating the economic significance of the catalyst or intermediate to the firm and certifying that the described operating and exposure conditions would not be altered. Information on chemicals meeting these conditions would be placed in a separate EPA file, which would not be revealed to outside parties without permission from the certifying individual. 1/ The consequences of this procedure would mean that firms seeking information on chemical catalysts and

1/ Of course, this suggestion would be viable only if it were consistent with legal requirements under the Freedom of Information Act.

intermediates of their competitors would not be assisted by the TSCA inventory. They would have the same avenues of research available as before. Furthermore, EPA would have all the information it desired to ensure that all confidential chemicals (listed and otherwise) were safe.

All chemicals certified to be confidential but not meeting the above strict conditions would be listed in the manner described by EPA with the following exception. Inquiries about those listed, but confidential, chemicals would be required to describe the chemical completely. When inquiries for these chemicals were received by EPA, the listing party would be informed, giving the name of the inquirer.

While the modifications described here lack detail, we urge EPA to consider them as alternatives to the procedure described in the proposed regulations (42 FR 13137).

2. Premarket Notification and Foreign Patents

Under TSCA, chemical substances which are not listed on the proposed inventory will be subject to premarket notification. 1/ Consider a firm which may have reached a point in its product development activities where a "new" chemical has been developed and tested. In order to sell the chemical, the sponsoring firm will submit certain materials to EPA which describe the chemical and its intended use. Related research findings and scientific literature on the chemical will also be provided. EPA will review the materials submitted and publish a summary of the premarket notification materials in the Federal Register.

1/ Premarket notification is not defined in these proposed regulations. Our understanding of the process is described here and on p. 2.